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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,413	09/13/2000	Zafiris G. Zafirelis	CAT-11	7935

7590
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10/03/2003

EXAMINER

LE, HUYEN D

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,413

Applicant(s)

ZAFIRELIS ET AL.

Examiner

Huyen Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-29, 32-42, 44, 45 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9, 18-20, 24, 29, 32-34, 48, 51 and 52 is/are rejected.
- 7) ☒ Claim(s) 10-17, 21, 23, 25-28, 35-42, 44, 45, 49 and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-6, 29, 32-34, 48, 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirose et al (5,449,342).

The Hirose et al reference disclose a system for assisting flow of blood by a patient's heart comprising a transseptal cannula 1 adapted to be inserted in the femoral vein and extend through the atrial septum from the right atrium to the left atrium; a blood pump mechanism having an inlet connected to the transseptal cannula (Fig. 7), the blood pump including a transseptal clamp mechanism 5 for clamping the blood pump to the transseptal cannula 1; and a perfusion cannula 8 adapted to be inserted in the femoral artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula 8 connected to the blood pump outlet, the blood pump (col. 6, lines 1-3) attached to the outside body which is capable of being within three feet where the transseptal cannula 1 and the perfusion cannula 8.

In regard to claim 4, the blood mechanism includes tubing 3, 8 which connects the blood pump to the transseptal cannula 1 and the perfusion cannula 8 and the clamp mechanism 5.

In regard to claims 29 and 32-34, the method for assisting blood flow by a patient's heart is inherently performed during the operation of the system.

3. Claims 1-6, 29, 32-34, 48 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Fonger et al (5,190,528).

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The Fonger et al reference disclose a system for assisting flow of blood by a patient's heart comprising a transseptal cannula 3 adapted to be inserted in the femoral vein and extend through the atrial septum from the right atrium to the left atrium; a blood pump mechanism 37 (Fig. 7) an inlet connected to the transseptal cannula 3, the blood pump 37 including a transseptal clamp mechanism 19 (Figs. 2a and 2b) for clamping the blood pump 37 to the transseptal cannula 3; and a perfusion cannula 41 adapted to be inserted in the femoral artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula 41 connected to the blood pump outlet 37, wherein the blood pump 37 is capable of being disposed within three feet where the transseptal cannula 1 and the perfusion cannula 8.

In regard to claim 4, the blood mechanism includes tubing 3 which connects the blood pump 37 to the transseptal cannula 3 and the perfusion cannula 41 and the clamp mechanism.

In regard to claims 29 and 32-34, the method for assisting blood flow by a patient's heart is inherently performed during the operation of the system.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al (5,449,342).

Although the Hirose et al reference is not specific about the blood pump having a rotor and stator, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a blood pump such as a centrifugal pump (see col. 5, lines 59-60) that would inherently include a rotor and stator.

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6. Claims 8, 9, 18-20 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al (5,449,342) in view of Wampler (5,840,070).

Although the Hirose et al reference does not disclose that the system for assisting flow of blood include a controller for operating the blood pump, such an electronic controller is known in the pump art. Attention is directed to the Wampler reference which discloses an electronic controller 59 for controlling a blood pump (see col. 8, lines 56-64)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a controller for the Hirose et al pump in view of the teaching of Wampler for controlling and adjusting the speed of the pump.

In regard to claim 9, a centrifugal pump would inherently include an impeller.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al (5,449,342).

Although the Hirose et al reference does not disclose a holding mechanism which holds and attaches the blood pump to the patient, such a feature is conventional. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a holding mechanism for conveniently attaching the blood pump to a user.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (5,190,528).

Although the Hirose et al reference is not specific about the blood pump having a rotor and stator, it would have been obvious to one of ordinary skill in the art at the time that a blood pump such as a centrifugal pump (see col. 7, lines 45-46) would inherently include a rotor and stator.

9. Claims 8, 9, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (5,190,528) in view of Aboul-Hosn (6,083,260).

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Although the Fonger et al reference does not disclose that the system for assisting flow of blood include a controller for operating the blood pump, such an electronic controller is conventional in the pump art. Attention is directed to the Aboul-Hosn reference which discloses an electronic controller for controlling a blood pump (see col. 14, lines 36-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a controller for the Hirose et al pump in view of the teaching of Aboul-Hosn for controlling and adjusting the speed of the pump.

In regard to claim 9, a centrifugal pump would inherently include an impeller.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (5,190,528).

Although the Fonger et al reference does not disclose a holding mechanism which holds and attaches the blood pump to the patient, such a feature is conventional. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a holding mechanism for conveniently attaching the blood pump to a user.

Allowable Subject Matter

11. Claims 10-17, 21, 23, 25-28, 35-42, 44, 45, 49 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments filed in the Amendment (Paper no. 10) filed on July 16, 2003 have been fully considered but they are not persuasive.

Regarding applicant's arguments that Hirose and Fonger et al do not teach the blood pump within 3 ft where the transseptal cannula and perfusion cannula enter a patient, the specific location of the blood pump as claimed does not impose any structural limitation which is

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distinguishable over the Hirose blood pump. When installing a blood circulation system on a patient by inserting cannula or catheter from a groin of a patient, one of ordinary skill in the art would attach a blood pump to patient and connect the pump to the cannula as close as possible for efficient use of the pump and safety purposes.

Regarding applicant's arguments that Hirose and Fonger et al do not teach a clamp mechanism as claimed, since neither the specification nor the drawings of the present application show what specific structure of the clamp mechanism and how the clamp mechanism is secured or clamped to other part, the clamp mechanism does not distinguish over the Hirose and Fonger et al connectors.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

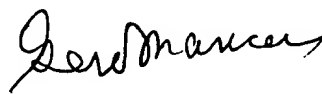
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huyen Le whose telephone number is 703-306-5504. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on 703-308-2580. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.

HL
October 1, 2003



Gene Mancene
Supervisory Patent Examiner
Group 3700
Supervisory Patent Examiner
Gene Mancene